

REMARKS

I. Summary of the Office Action

1. The Office Action rejected claims 1-27 under 35 U.S.C. §112, 2nd paragraph for allegedly using the term “amplification reagent” in a manner inconsistent with its art-accepted meaning.
2. The Office Action rejected claims 1-27 under 35 U.S.C. §101 for allegedly claiming the identical invention as prior U.S. Patent 6,203,989.

II. Response to the Office Action

Rejection of claims 1-27 under 35 U.S.C. §112, 2nd paragraph

The Office Action maintains the allegation that the use of the term “amplification reagent” in the claims is repugnant to the usual meaning of the term in the art because,

“in the biotechnology art, specifically in the class and subclass in which this application has been placed, (435/6), the accepted and well-known meaning of “amplification reagent” is a reagent that aids in the amplification of nucleic acids.”

Applicants respectfully disagree with the ground of rejection and submit that the rejection is due to a continued interpretation of the claims not made in light of the specification. It is respectfully pointed out that the Manual of Classification is not a lexicography guide, however, in the interest of advancing prosecution in the instant application, the claims have been amended to recite “signal amplification reagent.” While the amendment does not alter the scope of the claim when read in light of the specification, the addition of the term “signal” more clearly defines within the body of the claims exactly what the reagent is amplifying. The term “signal amplification” is an art-accepted term for increasing the signal intensity at a reaction site to aid in the identification of the reaction. This is evidenced by the disclosure of Stears *et al* (Physiol. Genomics, 3:93-99 (2000); attached as Appendix B), particularly in the abstract where it is stated

“[t]o improve signal detection on cDNA microarrays, we adapted a fluorescent oligonucleotide dendrimeric signal amplification system to microarray technology” (emphases added).

Accordingly, as used herein, the term “signal amplification reagent” is used in a manner consistent with an art accepted meaning to denote a reagent which “permits the detectable signal to be enhanced and more easily detectable” (page 3, lines 23-24, of the instant specification for example). Applicants respectfully request withdrawal of the ground of rejection.

Rejection of claims 1-27 under 35 U.S.C. §101 for claiming the same invention as claims 1-27 of U.S. Patent 6,203,989

The Office Action maintains that the claims are drawn to the identical invention as claims 1-27 of the ‘989 patent and therefore are subject to the double patenting provisions of 35 U.S.C. § 101. Applicants respectfully disagree with this position. In order for a claimed invention to be considered “the same” as another claimed invention and be subject to a statutory double patenting rejection, the claimed inventions must be identical. This is not the case in regard to the instantly claimed invention *versus* the invention claimed in the ‘989 patent. The instant claims require the presence of a “signal amplification reagent” in each of the base claims 1 (step c) and 23 (step d). In contrast, none of the claims of the ‘989 patent recite a “signal amplification reagent” as a limitation. In the further explanation of the grounds of rejection presented, the Office Action states that an adequate test for statutory double patenting is whether there is an embodiment that falls within the scope of one claim but not the other. The Office Action provides the example of “halogen” and “chlorine” and states that a claim reciting halogen “is not identical to or substantively the same as a claim reciting” chlorine because “halogen is broader than chlorine.” It is respectfully submitted that the instant application mirrors this example set forth in the Office Action, rather than the alternative example of “36 inches” versus “3 feet,” as the term “reagent” recited in the claims of the ‘989 patent is clearly broader than the term “signal amplification reagent” as used in the present claims. Further, the Office Action has erroneously read the limitations of dependent claims into the base claims, as evidenced by the statement, “the term ‘reagent’ is used to mean an antibody, or DNA matrix, or another element which will bind the reagent.” Applicants respectfully point out that none of those “elements” are recited in the base claim and therefore cannot be considered limitations thereof. Accordingly, Applicants assert that the claims are not drawn to the same invention, as the statute requires, and respectfully request withdrawal of the improper ground of rejection.

Conclusion.

In view of the foregoing remarks, the Applicants respectfully request withdrawal of all outstanding rejections and early notice of allowance to that effect. If the Examiner believes that allowance of this application may be expedited by a telephonic interview, she is encouraged to contact the undersigned.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

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Michael S. Tuscan, Ph.D.
Reg. No. 43,210

CUSTOMER NO. 000033522
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Ave., N.W.
Washington, DC 20004
202.739.3000 (voice)
202.739.3001 (fax)

APPENDIX A

Marked-Up Copy of the Claims

(Key: added text; [deleted text])

IN THE CLAIMS:

Please amend the claims as follows:

1. (Amended) A method for detecting a nucleic acid target comprising:
 - a) hybridizing a nucleic acid target, comprising a target nucleic acid sequence, to a nucleic acid probe, comprising a probe nucleic acid sequence, wherein the target comprises a binding ligand;
 - b) contacting the hybridized target with a receptor comprising multiple sites capable of binding the binding ligand to complex the receptor to the binding ligand;
 - c) contacting the receptor with an signal amplification reagent, comprising a plurality of the binding ligands, to complex the signal amplification reagent to the receptor; and
 - d) detecting the presence of the complexed signal amplification reagent.
2. (Amended) The method of claim 1, wherein the signal amplification reagent comprises an antibody.
3. (Amended) The method of claim 1, wherein the signal amplification reagent comprises a DNA matrix.
6. (Amended) The method of claim 1 wherein at least one of the receptor and the signal amplification reagent comprises a detectable label; and wherein step d) comprises detecting the label.
7. (Amended) The method of claim 1 further comprising labeling at least one of the receptor and the signal amplification reagent with a detectable label prior to step d); and wherein step d) comprises detecting the label.
8. (Amended) The method of claim 1 wherein the method further comprises, after step c), and before step d), the step of contacting the signal amplification reagent, comprising a plurality of the binding ligands, with labeled receptor molecules thereby to complex a plurality

of labeled receptor molecules to the signal amplification reagent; and

wherein step d) comprises detecting the labeled receptor molecules complexed to the signal amplification reagent.

12. (Amended) The method of claim 1, wherein the signal amplification reagent comprises an antibody capable of specifically binding the receptor.

15. (Amended) The method of claim 11, wherein the signal amplification reagent comprises a DNA matrix comprising single stranded DNA; and

wherein biotin is attached to the DNA matrix by hybridization of a plurality of biotinylated nucleic acids to single strands of the DNA matrix.

23. (Amended) A method for detecting a nucleic acid target, the method comprising:

a) providing a substrate comprising a surface, the surface comprising at least 100 nucleic acid probes, each nucleic acid probe contained in an area of less than about 0.1 cm^2 , and each nucleic acid probe having a defined sequence and location on the surface;

b) contacting the surface with a nucleic acid target, comprising a target nucleic acid sequence, to permit the nucleic acid target to hybridize with at least one selected nucleic acid probe that comprises a probe nucleic acid sequence capable of hybridizing to the target nucleic acid sequence, and wherein the target comprises a binding ligand;

c) contacting the hybridized target with a receptor comprising multiple sites capable of binding the binding ligand to complex the receptor to the binding ligand;

d) contacting the receptor with [an] a signal amplification reagent, comprising a plurality of the binding ligands, to complex the signal amplification reagent to the receptor; and

e) detecting the presence of the complexed signal amplification reagent.

26. (Amended) The method of claim 23, wherein the signal amplification reagent comprises a DNA matrix, the binding ligand comprises biotin and the receptor comprises streptavidin.

27. (Amended) The method of claim 26, wherein the binding ligand comprises biotin, the receptor comprises streptavidin and the signal amplification reagent comprises an anti-streptavidin antibody.

28. (Amended) A complex comprising:
a nucleic acid comprising a binding ligand;
a receptor comprising multiple binding sites capable of binding the binding ligand; and
an signal amplification reagent comprising a plurality of said binding ligands.

30. (Amended) The complex of claim 29, wherein the signal amplification reagent comprises a DNA matrix.

31. (Amended) The complex of claim 29, wherein the signal amplification reagent comprises an anti-streptavidin antibody.

34. (Amended) The substrate of claim 33, wherein the signal amplification reagent comprises a DNA matrix.

35. (Amended) The substrate of claim 33, wherein the signal amplification reagent comprises an anti-streptavidin antibody.